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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,155	01/16/2004	Douglas A. Hettrick	P-11316.00	9070

27581 7590 05/16/2006

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EXAMINER	
JOHNSON, SHEVON ELIZABETH	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary	Application No.	Applicant(s)	
	10/760,155	HETTRICK ET AL.	
	Examiner	Art Unit	
	Shevon E. Johnson	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/16/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/13/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7, 17-19, and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Thong et al. (U.S. Patent Pub. 2002/0120300), herein noted as Thong.

In regards to claim 1, Thong discloses a method (pg. 1, [0005-0006]) comprising: detecting atrial fibrillation (pg. 2, col. 2, [0014, 0015]); measuring hemodynamic performance during atrial fibrillation; and enabling therapy based on the measured hemodynamic performance (pg. 2, col. 2, [0018, 0019]).

In regards to claim 2, Thong discloses a method further comprising delivering the therapy when the therapy is enabled (pgs. 1-3, [0006, 0019]).

In regards to claim 3, Thong discloses a method wherein the therapy includes at least one of drug delivery, electrical stimulation, modification of ongoing electrical stimulation, and a combination of drug delivery and electrical stimulation (pg. 1, [0009]).

In regards to claims 4 and 17, Thong discloses a method wherein the therapy is atrial defibrillation therapy (pgs. 2-3, [0011, 0019]).

In regards to claim 5, Thong discloses a method wherein enabling therapy further comprises: determining whether hemodynamic compromise is present based on the hemodynamic performance during fibrillation; and enabling the therapy when hemodynamic compromise is present (pgs. 1-3, [0006, 0018, 0019]).

In regards to claim 7, Thong discloses a method further comprising withholding therapy when hemodynamic compromise is not present (pgs. 1-3, [0006, 0018, 0019]).

In regards to claim 18, Thong discloses a system for controlling application of therapy to a heart, the system comprising: a first sensor 1 that detects atrial fibrillation (pg. 2, [0014, 0015]); a second sensor 6 that measures hemodynamic performance during fibrillation (pg. 2, [0018]); and a processor 4 that

determines whether hemodynamic compromise is present based on the hemodynamic performance during atrial fibrillation, and enables delivery of therapy when hemodynamic compromise is present (pgs. 2-3, [0019]).

In regards to claim 19, Thong discloses a system wherein the therapy is withheld when hemodynamic compromise is not present (pgs. 1-3, [0005, 0006, 0019]).

In regards to claim 32, Thong discloses a system for controlling application of therapy to a heart, the system comprising: means for detecting atrial fibrillation (pg. 2, [0014, 0015]); means for measuring hemodynamic performance during fibrillation (pg. 2, [0018]); means for determining whether hemodynamic compromise is present based on the measured hemodynamic performance (pg. 2-3, [0019]); and means for enabling delivery of therapy when hemodynamic compromise is present.

In regards to claim 33, Thong discloses a system wherein the therapy is atrial defibrillation therapy (pg. 2, [0011]).

In regards to claim 34, Thong discloses a system wherein the therapy includes at least one of drug delivery, electrical stimulation, and a combination of drug delivery and electrical stimulation (pg. 1-2, [0009, 0011, 0019]).

In regards to claim 35, Thong discloses a system wherein the hemodynamic performance is measured using at least one of electrogram (EGM), electrocardiogram (ECG), atrial pressure, ventricular pressure, arterial pressure, flow, pulmonary venous flow, acceleration, atrial dimension, ventricular dimension, thoracic impedance, intramyocardial impedance, velocity, QT interval, ST segment, blood oxygen content, myocardial oxygen consumption, change in right ventricular pressure versus time (dRVP/dt), and MVO2/PO2 (pg. 2, [0010]).

3. Claims 1-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (U.S. Patent No. 5,156,148).

In regards to claim 1, Cohen discloses a method comprising: detecting a heart malfunction (col. 7, lines 5-6) such as atrial fibrillation (col. 7, lines 32-37); measuring hemodynamic performance (col. 6, lines

25-28); and inherently enables therapy (col. 5, lines 14-26) based on the measured hemodynamic performance (col. 6, line 62 – col. 7, line 4), further described in the references cited by Cohen (col. 7, line 67 - col. 8, line 11).

In regards to claim 2, Cohen discloses a method further comprising delivering the therapy when the therapy is enabled (col. 7, lines 5-37; col. 8, lines 1-11).

In regards to claim 3, Cohen discloses a method wherein the therapy includes at least one of drug delivery, electrical stimulation, modification of ongoing electrical stimulation, and a combination of drug delivery and electrical stimulation (col. 7, lines 5-37).

In regards to claims 4 and 17, Cohen discloses a method wherein the therapy is atrial defibrillation therapy (col. 7, lines 5-37).

In regards to claim 5, Cohen discloses a method wherein enabling therapy further comprises: determining whether hemodynamic compromise is present based on the hemodynamic performance during fibrillation; and enabling the therapy when hemodynamic compromise is present (col. 6, lines 38-41, 62-68; col. 7, lines 1-4, 67-68; col. 8, lines 1-11).

In regards to claim 6, Cohen discloses a method comprising storing information about the hemodynamic compromise (col. 6, lines 38-51).

In regards to claim 7, Cohen discloses a method comprising withholding therapy when hemodynamic compromise is not present (col. 6, lines 52-61).

In regards to claim 8, Cohen discloses a method wherein determining whether hemodynamic compromise is present further comprises: measuring a hemodynamic performance baseline during normal sinus rhythm; comparing the hemodynamic performance during fibrillation to the hemodynamic performance baseline to determine whether a change in hemodynamic performance has occurred; and determining presence of hemodynamic compromise when the change exceeds a threshold (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 9, Cohen discloses a method wherein the hemodynamic performance baseline and the hemodynamic performance during fibrillation are measured using at least one hemodynamic performance parameter (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 10, Cohen discloses a method wherein the hemodynamic performance parameter includes at least one of electrogram (EGM), electrocardiogram (ECG), atrial pressure, ventricular pressure, arterial pressure, flow, pulmonary venous flow, acceleration, atrial dimension, ventricular dimension, thoracic impedance, intramyocardial impedance, velocity, QT interval, ST segment, blood oxygen content, myocardial oxygen consumption, change in right ventricular pressure versus time (dRVP/dt), and MVO2/PO2 (col. 7, lines 44-57).

In regards to claim 11, Cohen discloses a method wherein the hemodynamic performance baseline and the hemodynamic performance during fibrillation are each measured using a combination of at least two hemodynamic performance parameters (col. 6, lines 62-68; col. 7, lines 1-4, 44-57, 67-68; col. 8, lines 1-11).

In regards to claims 12-16, Cohen discloses the method substantially as claimed except wherein quantifying severity of or determining the presence of hemodynamic compromise when the change exceeds a threshold expressed as an absolute change (fixed), percentage change (varying), rate of change in hemodynamic performance (col. 7, line 67 - col. 8, line 11).

In regards to claim 18, Cohen discloses a system for controlling application of therapy to a heart, the system comprising: a first sensor 12 that detects atrial fibrillation (col. 6, lines 28-37); a second sensor 11 that measures hemodynamic performance during fibrillation (col. 6, lines 20-28); and a processor 13 that determines whether hemodynamic compromise is present based on the hemodynamic performance during atrial fibrillation, and enables delivery of therapy when hemodynamic compromise is present (col. 6, lines 38-41, 62-68; col. 7, lines 1-4, 67-68; col. 8, lines 1-11).

In regards to claim 19, Cohen discloses a system wherein the therapy is withheld when hemodynamic compromise is not present (col. 6, lines 38-41, 62-68; col. 7, lines 1-4, 67-68; col. 8, lines 1-11).

In regards to claim 20, Cohen discloses a system wherein the processor stores information about the hemodynamic compromise (col. 6, lines 38-51).

In regards to claim 21, Cohen discloses a system wherein the therapy includes at least one of drug delivery, electrical stimulation, modification of ongoing electrical stimulation, and a combination of drug delivery and electrical stimulation (col. 7, lines 5-37).

In regards to claim 22, Cohen discloses a system wherein the therapy is atrial defibrillation therapy (col. 7, lines 5-37).

In regards to claim 23, Cohen discloses a system wherein the second sensor further measures hemodynamic performance during normal sinus rhythm (col. 6, lines 52-61).

In regards to claim 24, Cohen discloses a system wherein the processor compares the hemodynamic performance during fibrillation to the hemodynamic performance during normal sinus rhythm to determine whether a change in hemodynamic performance has occurred, and to determine presence of hemodynamic compromise when the change exceeds a threshold (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 25, Cohen discloses a system wherein the hemodynamic performance during normal sinus rhythm and the hemodynamic performance during fibrillation are measured using at least one hemodynamic performance parameter (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 26, Cohen discloses a system wherein the hemodynamic performance parameter includes at least one of electrogram (EGM), electrocardiogram (ECG), atrial pressure, ventricular pressure, arterial pressure, flow, pulmonary venous flow, acceleration, atrial dimension, ventricular dimension, thoracic impedance, intramyocardial impedance, velocity, QT interval, ST segment, blood oxygen content, myocardial oxygen consumption, change in right ventricular pressure versus time (dRVP/dt), and MVO2/PO2 (col. 7, lines 44-57).

In regards to claim 27, Cohen discloses a system wherein the hemodynamic performance during normal sinus rhythm and the hemodynamic performance during fibrillation are measured using a

combination of at least two hemodynamic performance parameters (col. 6, lines 62-68; col. 7, lines 1-4, 44-57, 67-68; col. 8, lines 1-11).

In regards to claim 28, Cohen discloses a system wherein the threshold represents a specified minimum change in the hemodynamic performance during fibrillation compared to the hemodynamic performance during normal sinus rhythm (col. 6, line 62 – col. 7, line 4).

In regards to claim 29, Cohen discloses a system wherein the processor quantifies severity of hemodynamic compromise based on the measured hemodynamic performance (col. 6, line 62 – col. 7, line 4).

In regards to claim 30, Cohen discloses a system further including a telemetry device for wireless transmission of a message when hemodynamic compromise is present (col. 8, line 51 - col. 9, line 10).

In regards to claim 31, Cohen discloses a system further including a telemetry device for wireless transmission of a message upon delivery of therapy (col. 8, line 51 - col. 9, line 10).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (U.S. Patent No. 5,156,148) in view of Thong et al. (U.S. Patent Pub. 2002/0120300), as cited by the examiner.

In regards to claim 36, Cohen discloses a method of treating atrial fibrillation substantially as claimed except programming a time period. However, Thong discloses a method wherein programming a time period to automatically deliver the therapy (pg. 1, [0001]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method as taught by Cohen, by incorporating the time period as taught by Thong in order to regulate the delivery of therapy and prevent unnecessary pain.

In regards to claim 37, Cohen discloses wherein determining whether hemodynamic compromise is present includes detecting a specified minimum change in hemodynamic performance measured at the programmed time period compared to hemodynamic performance measured during normal sinus rhythm (col. 6, lines 20-28, 62-68; col. 7, lines 1-4, 44-57).

In regards to claim 38, Cohen discloses further comprising withholding therapy when hemodynamic compromise is not detected (col. 6, lines 52-61).

In regards to claim 39, Cohen discloses wherein the fibrillation is atrial fibrillation (col. 7, lines 18-37).

In regards to claim 40, Cohen discloses wherein the therapy is atrial defibrillation therapy (col. 7, lines 18-37).

In regards to claim 39, Cohen discloses wherein the therapy includes at least one of drug delivery, electrical stimulation, modification of ongoing electrical stimulation, and a combination of drug delivery and electrical stimulation.

In regards to claim 42, Cohen discloses a computer-readable medium (col. 6, lines 38-41) containing instructions for causing a processor to: detect fibrillation (col. 7, lines 29-37); measure hemodynamic performance during fibrillation (col. 6, lines 28-37); measure hemodynamic performance during normal sinus rhythm (col. 6, lines 52-61); compare the hemodynamic performance during fibrillation to the hemodynamic performance during normal sinus rhythm to determine whether a change in hemodynamic performance has occurred (col. 6, line 62 – col. 7, line 4); detecting presence of hemodynamic compromise when the change exceeds a threshold (col. 7, line 67 – col. 8, line 11); and enable delivery of therapy when hemodynamic compromise is present (col. 7, lines 5-37).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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